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| 10/018,390 | 09/09/2002 | Jan Dirk van der Klis | 5091US | 7882 |

7590 07/15/2003

Traskbritt
PO Box 2550
Salt Lake City, UT 84110

EXAMINER

PATTEN, PATRICIA A

| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,390

Applicant(s)

KLIS ET AL.

Examiner

Patricia A Patten

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11,13-16,18 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-11,13-16,18 and 22-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 6) ☐ Other: _____

DETAILED ACTION

Claims 1-11, 13-16, 18 and 22-25 are pending in the application and were examined on the merits.

Priority

This application lacks the necessary reference to the prior PCT application as well as the foreign priority document. A statement reading "This is a 371 PCT/NL00/00199, filed 03/24/2000 which claims foreign priority to European Application EP 99200916.7 filed 03/24/1999." should be entered following the title of the invention or as the first sentence of the specification.

Abstract

It is noted that the Abstract from PCT/NL00/00199 was used as the Abstract in this application.

Drawings

The drawings are objected to because they fail to correlate with the description of the Drawings as described on page 10 of the Specification (please also see the objection to the Specification *vide infra*). Further, 'immunisation' in Fig. 1 should properly read: 'immunization'.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to for the following reason:

The specification describes Figure 1 as showing chickens fed with defatted soy meal which increased plasma calcitriol levels. However, Figure 1 actually displays data which shows chickens which had been administered DHCC as an adjuvant. It appears that the description in the Specification does not correlate to the data presented in Figure 1. Applicants are asked to correct this defect in the Specification, and present a new 'Brief description of the Drawings' (as a part of the Specification) which clearly describes the data presented in Figure 1.

Appropriate correction is required.

Claim Objections

Claims 7, 15, 16 and 22 are objected to because of the following informalities:

Claim 7 recites 'The method of claim 1 wherein also phytate degradation...'. This phrase is grammatically awkward. A suggestion for amending the claim to overcome this objection is: '...wherein said inducing calcitriol synthesis activity further comprises increasing phytate degradation capacity'.

Claim 15 recites 'a supplement'. Because claim 13 only comprises one supplement, Applicant is asked to reword claim 15 to recite 'the supplement'. This appears to be a minor grammatical error.

Claim 16 recites 'enriched for a substance'. This is a minor grammatical error. A suggested change to overcome this objection is: 'enriched with a substance'.

Claim 22 recites 'antibiotics of an animal'. This is a minor grammatical error. A suggested change to overcome this objection is: 'antibiotics to an animal'.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 7 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 and 18 recite the broad

recitation 'animal', and the claims also recite 'poultry or pigs' (and 'pig and poultry' – claim 18) which is the narrower statement of the range/limitation. A suggestion to overcome these rejections is to write two new dependant claims which limit 'the animal' [the animals] to poultry or pigs (please see additional rejections under 35 USC 112 Second paragraph for further suggestions) .

Again, Claims 1 and 18 recite 'an animal' and then 'poultry or pigs' (claim 1) and 'pig and poultry' (claim 18). In addition to the rejection set *supra*, this phrase lacks antecedent basis because claim 1 had previously stated 'an animal' (singular) while the terms 'poultry' and 'pigs' are plural thus lacking antecedent basis in the respective claims. Further, claim 1 recites, '..wherein said animal is selected from a group of poultry or pigs'. This phrase constitutes improper Markush practice and renders the claim indefinite. Thus, upon entering any new dependant claim which narrows 'the animal' to 'poultry or pigs' it is suggested that either 1) the independent claim recite 'in animalss' rather than 'an animal', or limit the new dependent claims to 'a chicken' or 'a pig' for example. Further, in order to overcome the improper Markush group, Applicant should structure the claim in proper Markush format; i.e., ' 26. The method of claim 1 wherein said animal is selected from the group consisting of a chicken and a pig (alternatively, if Applicant amends claim 1 to recite 'in animals', the new dependant claim(s) may recite ' 26. The method of claim 1 wherein said animals are selected from the group consisting of poultry and pigs').

Claims 2 and 7 lack clear antecedent basis in claim 1 in that claims 2 and 7 recite 'the animal'. Because it is unclear if claim 1 is limited to poultry or pigs, or to an 'animal', it is not understood which 'animal' claims 2 and 7 are referring to.

Claim 2 recites 'further comprising feeding said animal a food'. This phrase is confusing in that it reads as if a step is occurring in addition to induction of calcitriol synthesis. The Specification teaches that calcitriol synthesis is induced via feeding poultry (or pigs) soy meal, and does not teach administration of a second substance which induces calcitriol synthesis. Thus, this claim is confusing in light of what is actually taught in the Specification. It is suggested that the claim be amended to read '...wherein inducing said calcitriol synthesis comprises feeding said poultry or pig a food capable of inducing calcitriol synthesis' in order overcome this rejection.

Claim 22 recites 'A method of reducing the dietary intake of antibiotics of an animal...'. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. In the Instant case, it is not simply the administration of the substance which induces calcitriol synthesis which reduces the dietary intake of antibiotics in an animal, since the administration of antibiotics to an animal is chiefly transpired via feeding the animal antibiotics. It is suggested that either 1) a step be included in the method which clearly states that the intake of antibiotics is lowered, or 2)

amend the preamble of the claim to recite 'A method for decreasing the dietary need of antibiotics in an animal'... in order to overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 13-16, 18 and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Glabe et al. (US 4,178,370) or Goff et al. (1995).

Claims 1-11, 13-16, 18 and 22-25 are drawn to methods for increasing immune competence and/or phytate degradation in poultry or pigs comprising inducing calcitriol synthesis. Claims are further drawn to wherein inducing calcitriol synthesis is manifested from feeding poultry or pigs a substance which comprises soy, a method for preparing a feed comprising supplementing a feed with a substance capable of inducing calcitriol synthesis (soy), a supplement comprising a substance capable of inducing calcitriol synthesis (soy), a method for reducing the dietary intake of antibiotics to a

mammal comprising administering to the animal a food comprising a substance capable of inducing calcitriol.

Glabe et al. (US 4,178,370) disclosed an animal feed comprising soy meal which was fed to pigs (col.2, lines 38-47). It is well known that Soy beans (which are milled into soy meal) inherently contain phytoestrogens as taught in the Instant specification (p.3) . Because the soy meal was fed to the pigs, the soy must have inherently performed the claimed methods according to claims 1-7 , 18 and 22-25; i.e., 'increasing immune competence' and/or increasing phytate degradation or reducing dietary intake of antibiotics:

In re Sussman, 141 F. 2d 267, 60 U.S.P.Q. 538 (CCPA 1944): held that "...since the steps are the same, the results must inherently be the same unless they are due to conditions not recited in the claims." In the particular case, Applicants are claiming methods for increasing immune competence, increasing phytate degradation and reducing dietary intake of antibiotics via increasing calcitriol synthesis, wherein some dependant claims state wherein a phytoestrogen containing substance is administered to manifest the increased calcitriol synthesis. Glabe et al. clearly taught administration of a phytoestrogen containing substance; soy. Therefore, administration of the soy would have inherently manifested each of the intended uses of the claimed methods.

With regard to claims 8-11, Glabe et al. explicitly taught preparing the feed by mixing soy meal with other ingredients such as cornmeal (col.2). Therefore, these claims are anticipated.

It is noted that that the soy meal disclosed by Glabe et al. anticipates 'the substance' as described in the claims in that soy meal (the substance) comprises phytoestrogens, and soy meal is derived from a leguminous seed (soy).

Because soy meal is known, and because soymeal is known to inherently contain phytoestrogens, claims 13-16 are anticipated by Glabe et al.

Goff et al. (1995) examined cholecalciferol supplementation to poultry (Abstract). Specifically, Goff et al. examined plasma concentration of 1, 25-dihydroxycholecalciferol (calcitriol) in chickens fed with diets with or without corn-soybean meal at different concentrations of cholecalciferol (Table 1 and Materials and Methods). Therefore, Goff et al. anticipated the claims for the reasoning set forth *supra*. The only requirement of the claims is to induce calcitriol synthesis. The Instant specification teaches that calcitriol synthesis is increased naturally when chickens are fed soymeal. Thus, the increase of calcitriol synthesis was an inherent manifestation of the chickens ingesting the soy meal as described by Goff et al. Goff et al. further showed that calcitriol plasma levels were increased with the corn-soybean meal without cholecalciferol supplementation. To reiterate, soy inherently contains phytoestrogens.

Again, the method for preparing as recited in claims 8-11 are anticipated since Goff et al. clearly added (supplemented) soy meal to the feed composition. It is noted again that that the soy meal disclosed by Glabe et al. anticipates 'the substance' as described in the claims in that soy meal (the substance) comprises phytoestrogens, and soy meal is derived from a leguminous seed (soy). The composition claims (13-16) are clearly anticipated since the feed composition comprised soy meal which inherently contains phytoestrogens.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

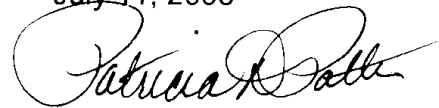
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. The official After final fax phone number is (703) 872-9307.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

July 11, 2003

A handwritten signature in black ink, appearing to read "Patricia Patten", written in a cursive style.

Patricia Patten